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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/062,587	01/31/2002	Harvey D. Preisler	047940-0135	1948
23524	7590	05/05/2006	EXAMINER	
FOLEY & LARDNER LLP 150 EAST GILMAN STREET P.O. BOX 1497 MADISON, WI 53701-1497			CANELLA, KAREN A	
			ART UNIT	PAPER NUMBER
			1643	

DATE MAILED: 05/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/062,587	Applicant(s) PREISLER, HARVEY D.	
	Examiner Karen A. Canella	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1, 3-21, 33 and 55-62, 73-83 and 85-90 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 1, 3-21, 33 is/are allowed.
- 6) ☐ Claim(s) 55-62, 73-82 and 86 is/are rejected.
- 7) ☐ Claim(s) 83, 85 and 87-90 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

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DETAILED ACTION

Claims 63-72 and 84 have been canceled. Claims 21, 55 and 83 have been amended. Claims 85-90 have been added. Claims 1, 3-21, 33 and 55-62, 73-83 and 85-90 are pending and under consideration.

Sections of Title 35, U.S. Code not found in this action can be found in a prior action.

Claim 88 is objected to because of the following informalities: the apparent typographical error of SEQ ID NO:26-23, rather than SEQ ID NO:26-31. Appropriate correction is required.

Claims 83, 85, 86, 87, 89 and 90 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claims require the specific peptides of SEQ ID NO: 1-3, 7-9, 13, 15, 16, 19-23 and 28-31, however, the sequences of claim 55 require that SEQ ID NO: 1-3, 7-9, 13, 15, 16, and 19-23 have one conservative amino acid substitution, and the sequence of claim 88 require that SEQ ID NO:26-31 have one conservative amino acid substitution, therefore the actual un-substituted sequences of SEQ ID NO: 1-3, 7-9, 13, 15, 16, 19-23 and 28-31 are not included in the scope of claims 55 or 88, or claims dependent therefrom.

Claims 55-62, 73-82, 86 and 87 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

(A) Claims 55-62 and 73-82 are drawn to isolated polypeptides which minimally comprise SEQ ID NO:1-23 having one conservative amino acid substitution, wherein the polypeptide binds to acute myeloid leukemia cells. It is noted that SEQ ID NO:7, 9-14, 17, 18, 20 and 23 are the sequences of SEQ ID NO:1-6, 15, 16, 19, 21 and 22 with the addition of a Cys at the amino and carboxyl termini. Only one variant was described by the specification, that of

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SEQ ID NO:8, wherein the Arg at residue 6 of SEQ ID NO:3 which is residue 7 of SEQ ID NO:7 is substituted with Aln. Claim 88 is drawn to isolated polypeptides which minimally comprise SEQ ID NO:26-23[31] having one conservative amino acid substitution, wherein the polypeptide binds to normal bone marrow cells, but not to acute leukemia cells.

The originally filed disclosure describes SEQ ID NO:1, 2, 3, 15, 16 and 22 as binding to both Acute myeloid leukemia cells and chronic myeloid leukemia cells, but not to normal bone marrow, CD34+ cells or lymphocytes or granulocytes (page 35, paragraph [0145]). The disclosure describes SEQ ID NO:4-6, 19 and 21 as binding to all myeloid cells, both malignant and nonmalignant paragraph [0150] which additionally is a property of SEQ ID NO:1-3, 15, 16 and 22 paragraph [0150]. Thus, amendment of claim 55 to specify that the conservative variant bind to acute myeloid leukemia cells is not supported by the specification as filed, because the limitation would also include peptides which bind selectively to acute myeloid leukemia cells to the exclusion of chronic myeloid leukemia cells, or the exclusion of normal myeloid cells, and the specification does not provide a single peptide which would bind in a specific manner to acute myeloid leukemia cells to the exclusion of either chronic myeloid leukemia cells or normal myeloid cells. It is noted that SEQ ID NO:4 bind to chronic lymphocytic leukemia cells but does not bind to normal peripheral granulocytes or normal lymphocytes, and that SEQ ID NO:16 binds to both chronic and acute myeloid leukemia cells but not to normal bone marrow, CD34+ cells, normal lymphocytes or granulocytes. One of skill in the art would reasonably conclude that applicant was not in possession of the claimed variants having the recited properties at the time of filing.

(B) Claim 86 is drawn to an isolated peptide of claim 55, wherein said peptide induces differentiation of AML cells into mature blood cells that perform normal blood cell function wherein the polypeptide comprises SEQ ID NO:1-3, 7-9, 13, 15, 16, 21 or 22. The originally filed disclosure describes the “free” G5 12B and A2 11-24 peptides which stimulate differentiation of myeloid leukemia cells. It is assumed that the “free” peptides are peptides not displayed by phage, and therefore are lacking the Cys residues that flank the sequence. SEQ ID NO:1 (page 11, second line from bottom) and SEQ ID NO:3 (page 12, line 3) have the indicated G5 12B and A2 11-24 sequences. The disclosure that these two peptides are able to induce differentiation of myeloid leukemia cells does not provide support for the two peptides inducing

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differentiation of acute myeloid leukemia cells. Neither does this data provide support for any of SEQ ID NO:2, 7-9, 13, 15, 16, 21 or 22 having the property of inducing differentiation of AML cells. One of skill in the art would reasonably conclude that applicant was not in possession of the claimed invention at the time of filing.

All other objections and rejections as set forth or maintained in the previous Office action are withdrawn in light of applicants amendments.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 11 am to 10 pm, except Wed, Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A. Canella, Ph.D.

4/29/2006


KAREN A. CANELLA PH.D.
PRIMARY EXAMINER